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09/600,602 10/03/00 UEKI

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EXAMINER

LOEB, R

ART UNIT

PAPER NUMBER

1636

DATE MAILED:

10/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/600,602

Applicant(s)

UEKI, JUN

Examiner

Bronwen M. Loeb

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7,9-14,16-18 and 21-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) Claims 1, 2, 4-7, 13, 14, 21, 22, 24-26, 28 and 29 is/are rejected.
- 7) ☒ Claim(s) 9-12, 16-18, 23, 27 and 30-32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This action is in response to the amendment filed June 28, 2001, in which claims 3, 8, 15, 19 and 20 were cancelled, claims 1, 2, 4, 6, 7, 9-14 and 16-18 were amended and new claims 21-32 were submitted.

Any rejection in any previous action not repeated herein has been withdrawn.

Claims 1, 2, 4-7, 9-14, 16-18 and 21-32 are pending.

Response to Arguments

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 1, 2, 4, 6, 7, 13, 14, 26, 28 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Morioka et al (USP 5,801,016). This rejection is maintained for reasons of record set forth in Paper No. 11, mailed February 28, 2001 and extended to new claims as necessitated by Applicant's amendment filed June 28, 2001.

Applicant's arguments filed June 28, 2001 have been fully considered but they are not deemed to be persuasive. Morioka et al teach an isolated nucleic acid fragment comprising the nucleotide sequence shown in SEQ ID No. 1. See Abstract, col. 1, lines 41-48, col. 2, lines 49-58 and col. 3, lines 27-33. Specifically, Morioka et al teach an

isolated nucleic acid fragment comprising the sequence shown in that reference's SEQ ID No. 1 (which is the same as SEQ ID No. 3 in the instant specification) except that one or a plurality of nucleotides are added, inserted, deleted or substituted and which has the function to promote expression of a gene downstream thereof. Morioka et al teach a recombinant vector comprising the isolated nucleic acid fragment comprising the nucleotide sequence shown in SEQ ID No. 1, as well as a method for promoting expression of a structural gene. See col. 1, lines 48-56, col. 4, lines 2-20 and col. 10, lines 6-39. Morioka et al also teach the method wherein the nucleic acid is in a plant. See col. 10, lines 6-39.

Applicant argues that by amending the independent claims 1, 6 and 13 to incorporate the limitation of claim 3, the rejections of the claims over the prior art is overcome. This is not found persuasive as the limitation of claim 3 was incorporated into the respective independent claims only with respect to the first species claimed. Therefore, the second species is still anticipated by Morioka et al and the rejection is maintained.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 2, 4-7, 13, 14, 21, 22, 26, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morioka et al as applied to claims 1, 2, 4, 6-9, 13-16 and 20 above, in view of Ueki et al (Plant Cell Physiol. (1999) 40(6): 618-623). This rejection is maintained for reasons of record set forth in Paper No. 11, mailed February 28, 2001 and extended to new claims as necessitated by Applicant's amendment filed June 28, 2001.

Applicant's arguments filed June 28, 2001 have been fully considered but they are not deemed to be persuasive. Morioka et al is applied as above. Morioka et al do not teach: a nucleic acid comprising a plurality of nucleic acid fragments which comprise the recited nucleotide sequence, said fragments being ligated; also a method for promoting expression of a structural gene comprising inserting a plurality of nucleic acid fragments which comprise the recited nucleotide sequence, said fragments being ligated at a location upstream of a structural gene. Ueki et al teach a nucleic acid comprising a plurality of nucleic acid fragments which comprise the recited nucleotide sequence, said fragments being ligated. Ueki et al also teach a method for promoting expression of a structural gene comprising inserting a plurality of nucleic acid fragments which comprise the recited nucleotide sequence, said fragments being ligated, at a location upstream of a structural gene. See Abstract, p. 620, Figs. 1 and 2. At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the teachings of Morioka et al with the plural introns taught by Ueki et al. One of ordinary skill in the art would have been motivated to do so because both references teach the expression promoting function of the first intron of rice PLD gene, and Ueki et al

demonstrate an increase in expression in the two intron construct compared to a single intron construct (p. 620, Fig. 2).

Applicant argues that by amending the independent claims 1, 6 and 13 to incorporate the limitation of claim 3, the rejections of the claims over the prior art is overcome. There is no argument specifically addressing this obviousness rejection. Therefore, this is not found persuasive as the limitation of claim 3 was incorporated into the respective independent claims only with respect to the first species claimed. The second species is still anticipated by Morioka et al and the obviousness rejection is maintained.

5. Claims 1, 2, 4-7, 13, 14, 21, 22, 26, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morioka et al as applied to claims 1, 2, 4, 6-9, 13-16 and 20 above, in view of Ueki et al (EP 0846770 A1; "Ueki et al EP"). This rejection is maintained for reasons of record set forth in Paper No. 11, mailed February 28, 2001 and extended to new claims as necessitated by Applicant's amendment filed June 28, 2001.

Applicant's arguments filed June 28, 2001 have been fully considered but they are not deemed to be persuasive. Morioka et al is applied as above. Morioka et al do not teach: a nucleic acid comprising a plurality of nucleic acid fragments which comprise the recited nucleotide sequence, said fragments being ligated; also a method for promoting expression of a structural gene comprising inserting a plurality of nucleic acid fragments which comprise the recited nucleotide sequence, said fragments being ligated, at a location upstream of a structural gene. Ueki et al EP teach a nucleic acid comprising a

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plurality of nucleic acid fragments which comprise the recited nucleotide sequence, said fragments being ligated. Ueki et al EP also teach a method for promoting expression of a structural gene comprising inserting a plurality of nucleic acid fragments which comprise the recited nucleotide sequence, said fragments being ligated, at a location upstream of a structural gene. See Abstract, p.4 lines 2-9 and 30-57, and p. 5, Table 1. At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the teachings of Morioka et al with the plural introns taught by Ueki et al EP. One of ordinary skill in the art would have been motivated to do so because both references teach the expression promoting function of the first intron of rice PLD gene, and Ueki et al EP demonstrate an increase in expression in the two intron construct compared to a single intron construct (p. 5, Table 1).

Applicant argues that by amending the independent claims 1, 6 and 13 to incorporate the limitation of claim 3, the rejections of the claims over the prior art is overcome. There is no argument specifically addressing this obviousness rejection. Therefore, this is not found persuasive as the limitation of claim 3 was incorporated into the respective independent claims only with respect to the first species claimed. The second species is still anticipated by Morioka et al and the obviousness rejection is maintained.

NEW REJECTIONS

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24 and 25 are vague and indefinite in reciting "is inserted upstream of said structural gene". It is unclear with respect to the intron insertion recited in claim 17, upon which both of these claims depend, where the plurality is inserted.

Conclusion

Claims 1, 2, 4-7, 13, 14, 21, 22, 24-26, 28 and 29 are rejected. Claims 9-12, 16-18, 23-25, 27 and 30-32 are free of prior art.

Claims 9-12, 16-18, 23, 27 and 30-32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 10:00 AM to 6:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to Dianiece Jacobs, Patent Analyst whose telephone number is (703) 305-3388.

Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636

October 1, 2001


ROBERT A. SCHWARTZMAN
PRIMARY EXAMINER